

## 专利合作条约

## PCT

国际初步审查报告  
(PCT 条约 36 和细则 70)

RECEIVED	
31 AUG 2004	
WIPO	PCT

申请人或代理人的档案号 SY-03-P-07	关于后续行为 参见“传送国际初步审查报告的通知”(PCT/IPEA/416 表)	
国际申请号 PCT/CN03/00290	国际申请日(日/月/年) 21.4 月 2003(21.04.03)	优先权日(日/月/年) 23.4 月 2002(23.04.02)
国际专利分类(IPC)或者国家分类和 IPC 两种分类 A61K35/78, 9/19, A61P9/00, 27/00		
申请人 张瑞香		

1. 本国际初步审查单位已作出国际初步审查报告并依照条约第 36 条将其传送给申请人。

2. 本报告共计 3 页, 包括扉页。

本报告还有附件, 即修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页, 和/或对本国际初步审查单位所作出的更正页(见 PCT 细则 70.16 和行政规程 607)。

这些附件共计 \_\_\_\_ 页

3. 本报告包括关于下列各项的内容:

I  报告的基础

II  优先权

III  不作出关于新颖性、创造性和工业实用性的意见

IV  缺乏发明的单一性

V  按条约 35(2)关于新颖性、创造性或工业实用性的推断性意见; 支持这种意见的引证和解释

VI  引用的某些文件

VII  国际申请中的某些缺陷

VIII  对国际申请的某些意见

提交要求书的日期 11.8 月 2003(11.08.03)	完成本报告的日期 12.8 月 2004(12.08.04)
国际初步审查单位名称和地址 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号: 86-10-62019451	受权官员 沈丽鸽 电话号码: (86-10)-62085337 

## I. 报告的基础

## 1. 关于国际申请中各个部分: \*

 原始提交的国际申请。

说明书, 第 \_\_\_\_\_ 页, 原始提交的,  
 第 \_\_\_\_\_ 页, 要求书提交的,  
 第 \_\_\_\_\_ 页, \_\_\_\_\_ 的信件提交的。  
 权利要求, 第 \_\_\_\_\_ 页, 原始提交的,  
 第 \_\_\_\_\_ 页, 条约第 19 条修理工改的(附有说明),  
 第 \_\_\_\_\_ 页, 要求书提交的。  
 第 \_\_\_\_\_ 页, \_\_\_\_\_ 的信件提交的。

附图, 第 \_\_\_\_\_ 页, 原始提交的,  
 第 \_\_\_\_\_ 页, 随要求书提交的,  
 第 \_\_\_\_\_ 页, \_\_\_\_\_ 的信件提交的。

说明书中的序列表部分  
 第 \_\_\_\_\_ 页, 原始要求提交的,  
 第 \_\_\_\_\_ 页, 随要求书提交的,  
 第 \_\_\_\_\_ 页, \_\_\_\_\_ 的信件提交的。

## 2. 关于所使用的语言, 除本项下另有说明外, 本国际初步审查单位所获得的或者已向本国际初步审查单位提交的上述所有部分, 所使用的语言均为提交本国际申请时所使用的语言。

本国际初步审查单位所获得的或向本国际初步审查单位提交的这些部分所使用的语言是 \_\_\_\_\_, 这种语言是 \_\_\_\_\_

- 为了国际检索而提交的译本所使用的语言 (细则 23.1 (b))。
- 本国际申请公布时所使用的语言 (细则 48.3 (b))。
- 为了国际初步审查而提交的译本所使用的语言 (细则 55.2 和/或 55.3)。

## 3. 关于本国际申请中所公开的任何核苷酸和/或氨基酸的序列, 本国际初步审查是根据下面的序列表进行的:

- 国际申请中所包含的书写形式的序列表。
- 与国际申请同时提交的计算机可读形式的序列表。
- 后来以书写形式向本国际初步审查单位提交的序列表。
- 后来以计算机可读的形式向本国际初步审查单位提交的序列表。
- 已提交了关于后来提交的书写形式的序列表没有超出原始提交的国际申请所公开的范围的说明。
- 已提交了关于以计算机可读的形式记载的信息是与书写形式的序列表相同的说明。

## 4. 修改删除了以下内容的:

- 说明书, 第 \_\_\_\_\_ 页
- 权利要求, 第 \_\_\_\_\_ 项
- 附图, 第 \_\_\_\_\_ 页, 图 \_\_\_\_\_

5.  由于(某些)修改被认为超出了原始公开的范围, 如补充栏所示, 因此本报告是按照如同没有修改的情况作出的(细则 70.2(c))。\*\*

\* 按照条约第 14 条答复通知时向受理局提交的替换页, 在本报告中被称为“原始提交的”, 这些替换页不作为本报告的附件, 因为它们没有包含修改 (细则 70.16 和 70.17)。

\*\* 任何包含这种修改的替换页, 都必须在第 1 项中指明, 并作为本报告的附件。

## 国际初步审查报告

国际申请号

PCT/CN03/00290

## V. 按条约 35 条(2)关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释

## 1. 意见

新颖性(N)

权利要求

1-6

是

权利要求

否

创造性(IS)

权利要求

1-6

是

权利要求

否

工业实用性(IA)

权利要求

1-6

是

权利要求

否

## 2. 引证和解释（细则 70.7）

引用国际检索报告中的对比文件

D1=“苦碟子注射液”，中药制剂汇编（第一版），曹春林

D2=冷冻干燥，中药制剂学（第一版），曹春林

## 新颖性

由于现有技术（D1 和 D2）中没有公开权利要求 1 的产品主题，没有公开权利要求 2—6 的制备方法主题。因此，根据 PCT 法 33 (2)，权利要求 1—6 具备新颖性。

## 创造性

虽然 D1 中公开了苦碟子注射液，D2 中公开了冷冻干燥的步骤，但是，由于权利要求 1 的苦碟子冻干粉针剂克服了现有技术中腺苷和黄酮的成分易于损失的不足。因此，权利要求 1 的产品和权利要求 2 的制备方法均被认为是本领域技术人员非显而易见的。因此，权利要求 1 和 2 具有创造性，符合 PCT 第 33(3)条关于创造性的规定。从属权利要求 3—6 是权利要求 2 所述制备方法中稳定剂和支持剂的进一步限定，在权利要求 2 的创造性成立的前提下，权利要求 3—6 也具有创造性，符合 PCT 第 33(3)条关于创造性的规定。

## 工业实用性

权利要求 1—6 中的主题符合 PCT 法 33 (4) 规定的工业实用性。

Translation

## PATENT COOPERATION TREATY

PCT

31 AUG 2004

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SY-03-P-07	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CN03/00290	International filing date (day/month/year) 21. Apr. 2003(21.04.03)	Priority date (day/month/year) 23.Apr.2002 (23.04.02)
International Patent Classification (IPC) or national classification and IPC IPC(8): A61K35/78,9/19,A61P9/00,27/00		
<p><b>Applicant</b> ZHANG,Ruixiang</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>2</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and /or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority ( see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty ,inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2)with regard to novelty ,inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application.</p>		

Date of submission of the demand 11. Aug. 2003(11. 08. 03)	Date of completion of this report 12. Aug. 2004 (12. 08. 04)
Name and mailing address of the IPEA/CN 6 Xitucheng Rd., Jimen Bridge, Haidian District, 100088 Beijing, China Facsimile No. 86-10-62019451	<p>Authorized officer SHEN Liling</p> <p>Telephone No.(86-10)-62085337</p> <p></p>

## I. Basis of the report

## 1. With regard to the elements of the international application:

the international application as originally filed  
 the description:

pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the claims:

Nos \_\_\_\_\_, as originally filed  
 Nos \_\_\_\_\_, as amended (together with any statement) under Article 19  
 Nos \_\_\_\_\_, filed with the demand  
 Nos \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the drawings:

sheets/fig \_\_\_\_\_, as originally filed  
 sheets/fig \_\_\_\_\_, filed with the demand  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the sequence listing part of the description:

pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. with regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
 the language of publication of the international application (under Rule 48.3(b)).  
 the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority in written form.  
 furnished subsequently to this Authority in computer readable form.  
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims Nos. \_\_\_\_\_  
 the drawings, sheets/fig \_\_\_\_\_

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement:**

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

D1=Kudiezi injection , A Collection of formulations made from Chinese Material medica ,the 1<sup>st</sup> edition , Cao Chunling

D2= Refrigeration, the Pharmaceutics of Chinese Material medica, the 1<sup>st</sup> edition , Cao Chunling

**Novelty:**

The subject matter (product) of claim 1, and the subject matters (the preparation methods of the product) of claim 2-6 are novel under PCT Article 33(2), because the prior art (D1 and D2) did not disclose the lyophilized powder injection , in which the ratio of flavone to adenosine is 5mg : 15 $\mu$ g or 5mg: 30 $\mu$ g, and also did not disclose the preparation methods of it .

**Inventive step:**

Although D1 discloses a injection which is produced by Ixeris Sonchifolia and D2 discloses the method of refrigeration, but the prior art (D1 and D2) did not teach the lyophilized powder injection of claim 1, and, more important is, the lyophilized powder injection of claim 1 overcomes the discourage of the prior art , that is in the lyophilized powder injection of claim 1, the flavone and adenosine is more stable than in the liquid injection, so that it is easy to control the quality of the product and makes the medicament more safe and more effective. Thus, claims 1(the product) and claims 2-6 (the preparation methods of it ) meet the requirement of inventive step of Article 33(3)PCT .

**Industrial applicability :**

The subject matter of claims 1-6 fulfil the requirement of industrial applicability of Article 33(4)PCT .